

### **Remarks**

Claims 1, 7-10, 14, 17, 18, and 22-26 are pending in the subject application. These claims were elected by Applicant (response mailed November 21, 2003) in response to the restriction requirement mailed October 21, 2003. The Office has considered this election not fully responsive based on Applicant's failure to elect a single sequence identification number. Based on Applicant's new understanding of the Restriction Requirement, Applicant respectfully traverses the restriction requirement and presents a request for reconsideration.

### **Provisional election with traverse required under 37 C.F.R. §1.143**

Notwithstanding traversal on the merits, in compliance with 37 C.F.R. §1.143, Applicant elects SEQ ID NO. 5 with traverse for the reasons stated below. This election is also made to the extent that it is understood that (a) the restriction requirement as to the linked inventions will be withdrawn upon the allowance of the linking claim(s) 1, 3, 8, and 9-11 and (b) any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application.

### **Request for reconsideration of restriction requirement under 37 C.F.R. 1.143**

Applicant respectfully requests reconsideration and modification of this restriction requirement. By requiring the election of a single peptide sequence from a Markush group, the instant restriction is unreasonable and inconsistent. The presently claimed inventions are drawn to methods comprising detecting the amount of expression of a MART-1 protein. Dependent claims 17 and 18 set forth Markush groups comprising 13 specifically defined peptide sequences.

The Office has recently instituted a policy directed to improving restriction practice within TC 1600 as stated by the recent publication of the TC1600 Restriction Practice Action Plan (press release on October 6, 2003). This policy emphasizes the importance of the quality and consistency of restriction practice and recognizes the need for improvements in this complex technology unit. Pertinent to this policy, Applicant points out that the instant restriction is

inconsistent with previously issued restriction requirements for a related subject application that also contains Markush groups comprising peptide sequences<sup>1</sup>.

As stated by the Office, there are two criteria for a proper requirement for restriction between patentably distinct inventions, MPEP § 803. First, the inventions must be independent or distinct. Second, there must be a serious burden on the Examiner if restriction is required. The Examiner must examine the subject application on the merits even if it includes claims to distinct inventions if such an examination can be made without serious burden. Applicant asserts that the search of claims 1, 7-10, 14, 17, 18, and 22-26 does not comprise such a serious burden and further note that the Examiner has not established how searching the instant claims would present such a burden.

Dependent claims 17 and 18 each contain a Markush grouping comprising 13 specifically defined peptide sequences. According to MPEP § 803.02, the Examiner must examine all members of the Markush group in the claims on the merits even if they are directed to independent and distinct inventions, if the examination can be made without serious burden.

If the members of a Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. (MPEP § 803.02)

Applicant asserts that these dependent claims 17 and 18 can be searched without serious burden.

First, the Office is capable of readily performing sequence searches of peptide sequences. The peptide sequences present in the instant claims are relatively uncomplicated. They uniformly consist of only 9 amino acids. Many sequences share related characteristics such as shared anchor residues, e.g. SEQ ID NOS 3 and 5; or SEQ ID NOS 11 and 13. Additionally, Applicant has provided sequence listings for the instant sequences. These factors indicate that an examination of the peptide sequences contained in the Markush group of the instant claims can be reasonably performed.

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<sup>1</sup> A copy of the restriction requirement issued for related Application No. 09/922,405 on February 5, 2004 has been enclosed as Appendix A.

Second, Applicant notes that chemical cases with Markush groups, which often contain complicated chemical R group structures, are routinely searched without restriction. The instant claims do not contain complicated R groups. Rather, a search of the instant peptide sequences constitutes straight sequence searching. The different standard that the Office appears to be applying for Markush groups containing peptide structures is unsupported.

Third, the Office operates a policy wherein 10 nucleotide sequences constitute a reasonable number for examination purposes, MPEP § 803.04. This allows for the examination of up to ten independent and distinct sequences in a single application without restriction. There are no distinct limits on nucleotide sequence length and complexity in this policy, suggesting that potentially long or complicated sequences (likely longer and more complex than the 9-mer instant peptides) are considered reasonable to search.

Therefore, it appears that the Office readily recognizes that a search of a combination of 10 or more sequences does constitute a reasonable search and examination burden. Applicant points to the pertinent policy behind this decision from the MPEP:

Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of C.F.R. 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. (MPEP § 803.04)

Applicant asserts that it is reasonable to apply a similar policy to the search of inventions containing peptide sequences, whose searches are performed similarly.

Accordingly, Applicant respectfully requests that the current restriction requirement, under which Applicant would be required to prosecute up to thirteen separate patent applications at considerable cost, be modified or vacated. Applicant respectfully requests that the restriction be modified to allow for the search and examination of up to 10 peptide sequences together.

If this requirement is not modified and is made final by the Examiner, Applicant further reserves the right to petition from requirement for restriction under 37 C.F.R. §1.144.

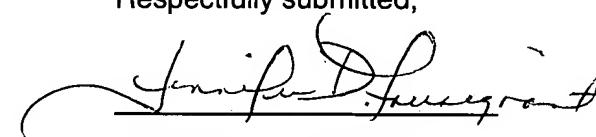
### Conclusion

No fee is deemed necessary in connection with the filing of this communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 07-1074.

Respectfully submitted,

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Date



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